UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/243,030	02/03/1999	MICHAEL GERARD TOVEY	23164-1001-D	1869

1444 7590 12/11/2003

BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
COOK, REBECCA	

ART UNIT	PAPER NUMBER
1614	30

DATE MAILED: 12/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/243,030	Applicant(s) TOVEY, MICHAEL GERARD	
	Examiner Rebecca Cook	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *18*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The finality of the office action of October 18, 2002 is withdrawn in view of the new rejections.

Claim Rejections - 35 USC § 112

Claims 36, 38-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is no antecedent basis in claim 36 for the proviso which recites "intranasally." There is no antecedent basis in claim 36 for the recitation "intranasally" in claims 39 and 40. Dorland's Medical Dictionary defines "oro-" as "combining form denoting relationship to the mouth." It is not seen how oromucosal would include intranasally.

When a rhinoviral infection is treated there is no antecedent basis in claim 36 for the dosage regimen in claim 38.

The intent of the recitation in claim 38 "administered in a single dose which is not a multiple or continuous dose" is not understood. Is the intent that the mammal receive only one dose and never again receive another dose?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over 5,286,748 (Eby, III). Eby (col. 4, lines 2-24, col. 8, lines 20-22) discloses a method of treating rhinovirus in a human by administering a lozenge to the oral mucosa comprising 20×10^6 IU of interferon. The instant claims differ over the Eby in reciting greater than about 20×10^6 of interferon. However, it would be obvious to one of ordinary skill in the art that the amount of interferon in the lozenge would not have exactly 20×10^6 IU of interferon. Some lozenges would have more interferon and would therefore have "greater than about 20×10^6 of interferon."

Claims 22-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/21229 (Amgen).

Amgen discloses a method of treating viral infections (abstract, page 5, lines 26-31, page 13, lines 20-27) using greater than about 20×10^6 of interferon.

Instant independent claims 36 and 37 differ over Amgen in reciting "oromucosal contact."

However, Amgen discloses (page 13, line 27) that the interferon can be administered nasally and it is well known that a product administered intranasally will contact the oromucosa. Furthermore, it is clear from the recitation in claim 36 "intranasally" and in the specification (page 12, lines 15-19) that nasal administration is contemplated in the instant invention.

Claims 22-24 and 38-40 differ over Amgen in reciting specific dosage regimens. However, once a method of use is known it is within the skill of the artisan to determine the optimum dosage regimen.

Claims 28 and 44-45 differ over Amgen in reciting type II interferon. However, in the absence of a showing of unexpected results, no unobviousness is seen in the use of type II interferon. Amgen (page 1, lines 13-18) discloses that interferons exhibit antiviral activity and grouped into three classes, which include IFN-α (Type I) and IFN-γ (Type II).

Claims 30-32 and 46-48 differ over Amgen in the dosages that they recite. However, once a method of use of a compound is known it is within the skill of the artisan to determine the optimum dosage.

Claims 35 and 51 differ over Amgen in reciting specific viral conditions. However, Amgen (page 5, lines 26-27) recite that the viral conditions treatable by IFN are not limited to the ones recited in the reference.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 22-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 93/21229 (Amgen) in view of CA 1,297,788 (Feinberg).

Amgen discloses a method of treating viral infections (abstract, page 5, lines 26-31, page 13, lines 20-27) using greater than about 30×10^6 of interferon.

Instant independent claims 36 and 37 differ over Amgen in reciting "oromucosal contact."

However, Amgen discloses (page 13, line 27) that the interferon can be administered nasally and it is well known that a product administered intranasally will contact the oromucosa. Furthermore, it is clear from the recitation in claim 36 "intranasally" and in the specification (page 12, lines 15-19) that nasal administration is contemplated in the instant invention.

Claims 22-24 and 38-40 differ over Amgen in reciting specific dosage regimens. However, Feinberg (page 4, paragraph five) discloses that interferon can be administered daily. Furthermore, once a method of use is known it is within the skill of the artisan to determine the optimum dosage regimen.

Claims 28 and 44-45 differ over Amgen in reciting type II interferon. However, in the absence of a showing of unexpected results, no unobviousness is seen in the use of type II interferon. Amgen (page 1, lines 13-18) discloses that interferons exhibit antiviral activity and grouped into three classes, which include IFN-α (Type I) and IFN-γ (Type II). Feinberg (page 4, paragraph two) discloses the use of either interferon I or 2.

Claims 30-32 and 46-48 differ over Amgen in the dosages that they recite. However, Feinberg discloses (page 4, paragraph five) that 75×10^6 IU can be used. Furthermore, once a method of use of a compound is known it is within the skill of the artisan to determine the optimum dosage.

Claims 35 and 51 differ over Amgen in reciting specific viral conditions. However, Amgen (page 5, lines 26-27) recite that the viral conditions treatable by IFN are not limited to the ones recited in the reference.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (703) 308-4724. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

REBECCA COOK
PRIMARY EXAMINER
GROUP 1200/1614

December 8, 2003